

<b>National Imaging Associates, Inc.*</b>	
<b>Clinical guidelines</b> <b>CARDIAC RESYNCHRONIZATION THERAPY (CRT)</b>	<b>Original Date: February 2013</b>
<b>CPT Codes: 33221, 33224, 33225, 33231</b>	<b>Last Revised Date: <del>March-February</del> 202<del>21</del></b>
<b>Guideline Number: NIA_CG_320</b>	<b>Implementation Date: January 202<del>32</del></b>

## GENERAL INFORMATION

It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.

## INDICATIONS FOR CARDIAC RESYNCHRONIZATION THERAPY (CRT)<sup>1-8</sup>

(Brignole, 2013; Cleland, 2005; Epstein, 2013; Ponikowski, 2016; Russo, 2013; Yancy, 2013)  
Indications for CRT for patients are based upon LV ejection fraction (LVEF), QRS duration, - New York Heart Association (NYHA) functional class (presence or absence of symptoms), and need for ventricular pacing regardless of etiology (ischemic or non-ischemic cardiomyopathy). The beneficial effects of CRT have been extensively proven in patients with NYHA class II, III, and IV; there is limited evidence of CRT benefit in patients with NYHA functional class I.

Hence, for the most part, CRT is recommended in only defined subsets of the HF patient population, the majority being symptomatic (NYHA class II-IV) HF patients in SR with a reduced LVEF and a QRS duration  $\geq$  130 ms. Other special situations, such as patients with atrial fibrillation or who require an upgrade from a conventional pacing or ICD system, will be addressed below as well.

### **Patients with cardiomyopathy on GDMT for 3 months or on GDMT and 40 days after MI; or with implantation of pacing or defibrillation device for special indications**

*CRT-D Indications By NYHA Heart Failure Class (see full definitions further below in document)*

- Class I: No limitation of functional activity:
  - LVEF  $\leq$  30%, QRS  $\geq$  150ms, LBBB, Sinus Rhythm
- Class II: Slight limitation of activity:

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- LVEF  $\leq$  35%, QRS  $\geq$  120ms, LBBB, Sinus Rhythm
- LVEF  $\leq$  35%, QRS  $\geq$  150ms, non-LBBB, Sinus Rhythm
- Class III and Ambulatory Class IV: Severe limitation of activity but not refractory to therapy
  - LVEF  $\leq$  35%, QRS  $\geq$  120ms, LBBB or non-LBBB, Sinus Rhythm

### Special Situations

- Independent/Regardless of NYHA Heart Failure Class
  - Patients with HFrEF ~~(36–50%)~~ <40% who have an indication for ventricular pacing and high degree AV block or are expected to be paced more than 40% of the time; this includes patients with Atrial fibrillation
- Atrial fibrillation and LVEF  $\leq$  35% ~~on GDMT~~ if:
  - Patient requires ventricular pacing or otherwise meets CRT criteria; AND
  - AV nodal ablation or pharmacologic rate control will allow nearly 100% ventricular pacing with CRT
- LVEF  $\leq$  35% and undergoing new or replacement device with anticipated requirement for significant (> 40%) ventricular pacing
- In patients with nonobstructive HCM who have NYHA class II to IV heart failure with LBBB, LVEF < 50%, CRT therapy for symptom reduction is reasonable

### NOT Indicated for Cardiac Resynchronization Therapy (CRT)

- NYHA class I and non-LBBB pattern with QRS duration < 150 ms ~~(Epstein, 2012)~~,<sup>3</sup> except as in Special Situations section above
- Comorbidities and/or frailty expected to limit survival with good functional capacity to <1 year
- Active bloodstream infection
- Reversible causes are present, such as toxic-, metabolic- or tachycardic-mediated cardiomyopathy. Would require reassessment once the situation is corrected

### Indications for CRT in Adult Congenital Heart Disease<sup>9–11</sup>

~~(Hernandez-Madrid, 2018; Khairy, 2014; Stout, 2018)~~

#### Systemic LV

- Systemic LV EF  $\leq$  35%, sinus rhythm, wide QRS complex  $\geq$  1320 ms ~~with complete LBBB QRS morphology (spontaneous or paced)~~ and NYHA function Class II—~~ambulatory~~ IV

### Any Systemic V

- Systemic ventricle any EF (not restricted to  $\leq 35\%$ ), intrinsic narrow QRS complex, NYHA function Class I—~~ambulatory~~ IV and are undergoing new device placement or replacement with anticipated requirement for significant ( $>40\%$ ) ventricular pacing. ~~Single site pacing from the systemic ventricular apex/mid-lateral wall may be considered as alternative.~~

### Any CHD

- CRT may be considered for patients with a severe subpulmonary RV dysfunction and dilatation despite interventions to decrease RV volume overload, NYHA function Class II—ambulatory IV and wide QRS complex  $\geq 150$  ms due to a complete RBBB

NYHA function Class IV and severe ventricular dysfunction who would otherwise be candidates for heart transplantation or mechanical circulatory support

- ~~• Systemic ventricle any EF (not restricted to  $\leq 35\%$ ), with progression of systolic systemic ventricular dysfunction and/or dilatation or expectation of such development, function Class I—ambulatory IV with a wide QRS complex  $\geq 150$  ms (spontaneous or paced) who are undergoing other cardiac surgery, especially if thoracotomy access is needed for lead implantation~~
- ~~• Systemic RV~~
- ~~• Systemic RV EF  $\leq 35\%$ , wide QRS complex  $\geq 150$  ms with a complete RBBB QRS morphology (spontaneous or paced), and NYHA function Class II—ambulatory IV~~
- ~~• Systemic RV EF  $\leq 35\%$ , sinus rhythm, wide QRS complex (120—149 ms) with complete RBBB QRS morphology (spontaneous or paced), and NYHA function Class II—ambulatory IV~~
- ~~• Systemic RV and significant tricuspid valve regurgitation without a specific EF limit, wide QRS complex  $\geq 150$  ms with a complete RBBB QRS morphology (spontaneous or paced)~~

~~undergoing surgery for significant tricuspid valve regurgitation, NYHA function Class I—ambulatory IV~~

~~•~~

~~• Single Ventricle~~

~~• Single ventricle EF  $\leq$  35%, sinus rhythm, wide QRS complex any morphology  $\geq$  120ms (spontaneous or paced) and NYHA function Class II—ambulatory IV~~

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#### ~~Any CHD~~

~~• CRT may be considered for patients with a severe subpulmonary RV dysfunction and dilatation despite interventions to decrease RV volume overload, NYHA function Class II—ambulatory IV and wide QRS complex  $\geq$  150 ms due to a complete RBBB~~

~~• NYHA function Class IV and severe ventricular dysfunction who would otherwise be candidates for heart transplantation or mechanical circulatory support~~

#### **NOT Indicated for CRT in Adult Congenital Heart Disease**

~~• Patients with a narrow QRS complex ( $<$  120 ms)~~

- Patients whose co-morbidities and/or frailty limit survival with good functional capacity to less than 1 year

#### **INDICATIONS FOR CRT AS THE APPROPRIATE PACING MODALITY IN SPECIAL SITUATIONS WITH $<$ 3 MONTHS OF GDMT<sup>6, 12, 13</sup>**

~~(Katsumoto, 2014; Marine, 2018; Russo, 2013)~~

Criteria are met for a non-elective implantable cardioverter defibrillator (ICD) or ~~pacemaker, and pacemaker and~~ based upon the low likelihood of improvement in symptoms and adequate recovery of LVEF, despite less than 3 months GDMT for heart failure or  $<$  40 days post myocardial infarction or 3 months post revascularization, criteria for CRT are otherwise met. This avoids a second implantation procedure within less than 3 months.

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#### **BACKGROUND<sup>1, 3-6</sup>**

~~(Brignole, 2013; Epstein, 2013; Ponikowski, 2016; Russo, 2013; Yancy, 2013)~~

CRT, which paces the left and right ventricle in rapid sequence, also known as biventricular pacing, improves coordination of ventricular contraction in the presence of a wide QRS complex in systolic heart failure.

CRT improves cardiac function and quality of life, and it decreases cardiac events and mortality among appropriately chosen patients. In the proper patient population, improved survival in patients with CRT is can be greater than that provided by ICD insertion alone.

Guiding principles in the consideration of CRT:

- NYHA class is an important qualifying factor, with candidacy based on functional class, EF, and QRS duration.
- Bundle branch block or intraventricular conduction delay should be persistent, not rate-related (Russo, 2013).<sup>6</sup>
- GDMT should have been in place continuously for at least 3 months<sup>3-5</sup> (Epstein, 2012; Ponikowski, 2016; Yancy, 2013) and recovery of LVEF from myocardial infarction (40 days) if no intervening revascularization or > 3 months if revascularization was performed. Reversible causes (e.g., ischemia) should be excluded.
- The patient should have expected survival with reasonably good functional status for more than 1 year.<sup>3, 5, 10</sup> (Epstein, 2013; Khairy, 2014; Ponikowski, 2016).
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## OVERVIEW

### NYHA Class Definitions<sup>6, 14</sup>

(Goldman, 1981; Russo, 2013)

- Class I: ~~No~~: No limitation of functional activity. Ordinary physical activity does not cause symptoms of HF or only at levels of exertion that would limit normal individuals (patient can carry 24 pounds up 8 stairs, play basketball, and shovel soil).
- Class II: ~~Slight~~: Slight limitation of activity. Comfortable at rest but ordinary physical activity results in symptoms of HF (fatigue, palpitation, or dyspnea with moderate exercise (patient able to dance, garden, and walk 4 mph on level ground).
- Class III: ~~Marked~~: Marked limitation of activity. Comfortable at rest but less than ordinary activity causes symptoms of HF (fatigue, palpitation, or dyspnea with minimal activity) HF (patient able to shower, make bed, bowl or golf, dress, and walk 2.5 mph on level).
- Class IV: ~~Severe~~: Unable to carry on any physical activity without symptoms of HF, or symptoms of HF at rest limitation of activity. Symptoms even at rest, worse with activity (patient unable to comfortably perform any significant activity).

- ~~Ambulatory Class IV: Class IV heart failure that is not refractory due to fluid retention, frequent hospitalization for heart failure, or dependent on continuous intravenous inotropic therapy.~~

### Heart Block Definitions<sup>3</sup>

(Epstein, 2013)

- First Degree: All atrial beats are conducted to the ventricles, but with a delay of > 200 ms.
- Second Degree: ~~Intermittent~~; Intermittent failure of conduction of single beats from atrium to ventricles.
  - Type I: Conducted beats have variable conduction times from atrium to ventricles.
  - Type II: ~~Conducted~~; Conducted beats have uniform conduction times from atrium to ventricles.
  - Advanced: ~~Two~~; Two or more consecutive non-conducted beats (premature atrial beats might not normally be conducted).
- Third Degree: ~~No~~; No atrial beats are conducted from atrium to ventricle.

### Guideline-Directed (or Optimal) Medical Therapy in Heart Failure<sup>4, 15</sup>

(Yancy, 2013, 2017)

- Angiotensin converting enzyme inhibitor (ACE-I), angiotensin receptor blocker (ARB), or combined angiotensin receptor inhibitor and neprilysin inhibitor (ARNI)
- Beta blocker
- Other options/considerations for GDMT
  - Addition of loop diuretic for all NYHA class II – IV patients
  - Addition of hydralazine and nitrate for persistently symptomatic African Americans, NYHA class III-IV
  - Addition of an aldosterone antagonist, provided eGFR is  $\geq 30$  ml/min/1.73m<sup>2</sup> and K<sup>+</sup> < 5.0, NYHA class II-IV
  - Not required for consideration of CRT: Ivabradine for NYHA class II – III, when a beta blocker has failed to reduce a sinus rate to < 70 bpm.

### Abbreviations

ACE-I	Angiotensin converting enzyme inhibitor
<a href="#">ARB</a>	<a href="#">Angiotensin receptor blocker</a>
ARNI	Combined angiotensin receptor inhibitor and neprilysin inhibitor
AV	Atrioventricular
CAD	Coronary artery disease, same as ischemic heart disease
<a href="#">CHD</a>	<a href="#">Congenital heart disease</a>
CHF	Congestive heart failure
CRT	Cardiac resynchronization therapy (also known as biventricular pacing)
<a href="#">CRT-D</a>	<a href="#">Cardiac resynchronization therapy defibrillator</a>
<del><a href="#">CHD</a></del>	<del><a href="#">Congenital heart disease</a></del>
ECG	Electrocardiogram
EF	Ejection Fraction
eGFR	Estimated glomerular filtration rate
EPS	Electrophysiologic Study
GDMT	Guideline-Directed Medical Therapy
HCM	Hypertrophic Cardiomyopathy
HF	Heart <del>f</del> ailure
<a href="#">HFrEF</a>	<a href="#">Heart failure with reduced ejection fraction</a>
HV	His-ventricular
ICD	Implantable cardioverter-defibrillator
LBBB	Left bundle branch block
LV	Left ventricular/left ventricle
LVEF	Left ventricular ejection fraction
MI	Myocardial infarction
ms	Milliseconds
NYHA	New York Heart Association
RBBB	Right bundle branch block
RV	Right ventricle
<del><a href="#">STEMI</a></del>	<del><a href="#">ST-Elevation Myocardial Infarction</a></del>
SND	Sinus node dysfunction
<a href="#">SR</a>	<a href="#">Sinus rhythm</a>
<a href="#">STEMI</a>	<a href="#">ST-Elevation Myocardial Infarction</a>
VT	Ventricular tachycardia

## POLICY HISTORY

Date	Summary
<del><a href="#">March 2023</a></del> <a href="#">February 2022</a>	<ul style="list-style-type: none"> <li>• <a href="#">Added blood stream infection and reversibility as contraindication</a></li> <li>• <a href="#">-Reworded NYHA</a></li> <li><del>• <a href="#">-Removed single ventricle and RV</a></del></li> </ul>

	<ul style="list-style-type: none"> <li>• <del>Added 2021 ESC references</del></li> </ul>
March 2021	<ul style="list-style-type: none"> <li>• Added indication and reference for hypertrophic cardiomyopathy with reference</li> <li>• Added indication for patient with expected ventricular pacing &gt; 40% of the time</li> <li>• Updated /Reorganized Section: Patients with cardiomyopathy on GDMT for 3 months or on GDMT and 40 days after MI; or with implantation of pacing or defibrillation device for special indications</li> <li>• Updated /Reorganized Section: Indications for CRT in Adult Congenital Heart Disease</li> <li>• Updated Abbreviations Section</li> <li>• </li> </ul>
	<ul style="list-style-type: none"> <li>• Added general information section as Introduction which outlines requirements for documentation of pertinent office notes by a licensed clinician, and inclusion of laboratory testing and relevant imaging results for case review</li> <li>• Removed comment that single site pacing from the systemic ventricular apex or mid-lateral wall may be considered as an alternative from the indication systemic ventricular EF <math>\leq</math> 35%, intrinsic narrow QRS complex, NYHA class I to ambulatory class IV and undergoing new or replacement device implantation with anticipated requirement for significant (&gt;40%) ventricular pacing.</li> <li>• Removed the following from the Guideline Directed Medical Therapy section: Ivabradine listed as a class IIa recommendation, while others are class I recommendations. CRT trials antedated routine use of ivabradine.</li> </ul>
August 2019	<ul style="list-style-type: none"> <li>• Changed ms from 130 to 150 in indication: 'left ventricular ejection fraction (LVEF) <math>\leq</math> 35%, sinus rhythm, left bundle branch block (LBBB) with a QRS <math>\geq</math> 150 ms, and NYHA class II, III or ambulatory class IV symptoms on GDMT'</li> <li>• Added indication for LVEF <math>\leq</math> 35%, sinus rhythm, LBBB with a QRS duration 120 to 149 ms, and NYHA class II, III, or ambulatory class IV symptoms on GDMT</li> <li>• Changed ms from 130 to 150 in indication: 'LVEF <math>\leq</math> 35%, sinus rhythm, a non-LBBB pattern with a QRS duration <math>\geq</math> 150 ms, and NYHA III or ambulatory class IV symptoms on GDMT'</li> </ul>



	<ul style="list-style-type: none"> <li>• Revised indication to state that LVEF <math>\leq 35\%</math> and are undergoing new or replacement device placement with anticipated requirement for significant (<math>&gt; 40\%</math>) ventricular pacing</li> <li>• Removed indication for LVEF <math>\leq 30\%</math>, ischemic etiology of HF, sinus rhythm, LBBB with a QRS duration <math>\geq 150</math> ms, and NYHA class I on GDMT</li> <li>• Removed indication for LVEF <math>\leq 35\%</math>, sinus rhythm, a non LBBB pattern with a QRS duration <math>\geq 150</math> ms, and NYHA class II on GDMT</li> <li>• Adult congenital heart disease, added indication for systemic LVEF <math>\leq 35\%</math>, sinus rhythm, complete LBBB with a QRS complex 120 - 149 ms (spontaneous or paced), and NYHA class II to ambulatory IV</li> <li>• Adult congenital heart disease, removed the following indications: <ul style="list-style-type: none"> <li>○ Cardiac surgery with a QRS duration <math>&gt; 150</math> ms</li> <li>○ Systemic RV with significant tricuspid valve regurgitation</li> <li>○ Severe subpulmonic RV dysfunction</li> <li>○ Severe ventricular dysfunction and NYHA class IV in attempt to delay transplant or mechanical support</li> </ul> </li> <li>• The following statement has been revised to add 'or 3 months post-revascularization.' Criteria are met for a non-elective implantable cardioverter defibrillator (ICD) or a non-elective pacemaker, either initial or replacement, and based upon the low likelihood of improvement in symptoms and adequate recovery of LVEF, despite less than 3 months GDMT for heart failure or <math>&lt; 40</math> days post myocardial infarction or 3 months post revascularization, criteria for CRT are otherwise met. The following statement has been added: 'This avoids a second implantation procedure within less than 3 months.'</li> </ul>
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~~Reviewed / Approved by NIA Clinical Guideline Committee~~

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**Reviewed / Approved by NIA Clinical Guideline Committee**

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